

EETD and Human Subjects Research

How to Stay Out of Trouble

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What Trouble?

- Suspension of human subjects research funding:
 - Individually
 - Institutionally (Johns Hopkins, Duke, Chicago)
- Inability to publish unapproved research.
- Repayment of federal funds for unapproved research.
- Liability for experiment-related injuries.



What is Research?

- “Research” --a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- “Generalizable knowledge” --conclusions drawn from the results of systematic investigation that are disseminated (i.e., reports, articles, conference presentations).



When are human subjects involved?

- “Human Subject” --a living individual about whom an investigator conducting research obtains:
 - Data through an intervention or interaction with the individual, or
 - Identifiable private information (the subjects' identity is or may be ascertained by the investigator or associated with the data)



Basic Human Research Principles

From the Belmont Report

- Respect for persons (subjects right to choose)
- Beneficence
 - Do no harm (non-maleficence)
 - Maximize benefit, minimize risk
- Justice
 - Fidelity (fairness, equality)
 - Veracity (truthfulness)



What's So Hard About That?

- Selection of the subject pool
 - Co-workers
 - Employees of the agency/concern sponsoring the research
 - Vulnerable populations like children (even tangentially)
- Communication with potential participants
 - Recruitment
 - Obtaining Consent



What's So Hard About That?

- Risk Assessment

- Ask Yourself -- What could go wrong?
- Psycho-social and privacy risks as well as physical harms
- Have *all* risks been minimized consistent with good study design?

- Thinking about your responsibility for adverse outcomes.



Tricky Spots in EETD Research

- Building-wide interventions
 - Experimental building modifications
 - How can occupants opt out?
- Man-machine interface
 - Design and testing of stoves, thermostats, and other devices
 - Surveys/interviews require different protections than hands-on studies



Tricky Spots in EETD Research

- Gathering data and protecting privacy
 - Online surveys and identifiers
 - Home entry and privacy
 - Indirectly gathering information about someone's location, living style.
- Communicating results
 - To individual subjects
 - To subject groups
 - Professionally

Tricky Spots in EETD Research

- Risks of intervention
 - Electrical
 - Injury
 - Psychosocial: embarrassment, employability, reputation
 - Individual susceptibility issues.



Human Subjects Committee

- Five members, minimum
- 5 Scientists (plus alternates).
- One non-scientist community member, not affiliated with UC.
- One non-scientist, affiliated with UC.



What kind of review is needed?

- Exempt
 - Not covered by regulations
- Expedited
 - Minimal risk, well characterized
- Full
 - Novel risk
 - More than minimal risk



FAQs

- If my research is exempt, why do I still need a review?
Federal guidelines do not provide for an investigator to make an exempt determination;
Research involving subject contact may be exempt from the federal regs, but not from the Belmont principles.



FAQs

- Can a supervisor or employer require employees to participate in research?
 - No, participation in research is voluntary.



Have we had any problems so far?

- Yes
 - LBNL student employee shocked due to improperly wired outlet in residence.
 - Public school installation of monitoring equipment was damaged, caused electrical short.



Take Away Lessons

- These projects benefit from review from multiple points of view.
- Phone consultation with the HARC office early on can help save time.